

Message Text

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62

ORIGIN HEW-08

INFO OCT-01 ISO-00 SCI-06 NEA-14 EA-11 ARA-16 EUR-25 AID-20

AGR-20 IO-14 AF-10 DODE-00 MED-03 INT-08 CIAE-00

INR-10 NSAE-00 RSC-01 /167 R

66624

DRAFTED BY:DHEW/FDA:JRWEINROTH, M.D.

APPROVED BY:SCI/SA:MSBEAUBIEN

DHEW/OIH:MACODDING

NEA/RA:TGRANT

EA/RA:CCHAPMAN

ARA/NSC-IG:RJBLOOMFIELD

EUR/NSC-IG:JDRENDahl

----- 013425

R 241910Z JUN 74

FM SECSTATE WASHDC

TO AMEMBASSY KABUL

AMEMBASSY BUENOS AIRES

AMEMBASSY CANBERRA

AMEMBASSY NASSAU

AMEMBASSY BRIDGETOWN

AMEMBASSY BRASILIA

AMEMBASSY SANTIAGO

AMEMBASSY BOGOTA

AMEMBASSY SAN JOSE

AMEMBASSY QUITO

AMEMBASSY SAN SALVADOR

AMEMBASSY BONN

AMEMBASSY GUATEMALA

AMEMBASSY GEORGETOWN

AMEMBASSY REYKJAVIK

AMEMBASSY NEW DELHI

AMEMBASSY TEHRAN

AMEMBASSY DUBLIN

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY KINGSTON

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AMEMBASSY AMMAN

AMEMBASSY MEXICO
AMEMBASSY MANAGUA
AMEMBASSY PANAMA
AMEMBASSY MADRID
AMEMBASSY STOCKHOLM
AMEMBASSY BANGKOK
AMEMBASSY ANKARA
AMEMBASSY LONDON
AMEMBASSY CARACAS
AMCONSUL HAMILTON
AMCONSUL CURACAO
GUAM TRUST OFFICER
SAIPAN TRUST OFFICER
ADMINISTRATOR CANAL ZONE

UNCLAS STATE 135043

E.O. 11652: NA

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: RECALL OF MEDICAL DEVICE

1. FDA ADVISES THAT THE RICHARDS MANUFACTURING COMPANY,
1415 EAST BROOKS ROAD, MEMPHIS, TENNESSEE IS RECALLING THE
FOLLOWING CATALOG PRODUCT CODE ITEMS:

SHEA STAPES DRILL NO. 1260-NO LONGER BEING MANUFACTURED.
RICHARD STAPES-MASTOID DRILL NO. 1265
FOOT SWITCH NO. 23-0111
RICHARD STAPES MASTOID DRILL SET -NO. 13-015-NO LONGER BEING
MANUFACTURED.

ITEMS BEING RECALLED BECAUSE OF DESIGN DEFICIENCY, I.E.,
DRILL AND FOOT SWITCH CAN BE PLUGGED INTO THE WRONG JACKS
ON THE POWER LINE ADAPTOR (THE JACKS OF BOTH BEING
IDENTICAL AND INTERCHANGEABLE IN UNITS SHIPPED PRIOR TO
9/1/73) WITH THE POTENTIAL OF PERMITTING 40 VOLTS TO BE
PASSED THROUGH THE PATIENT IF THE PATIENT IS GROUNDED AND THE
PLUGS ARE REVERSED. THE CURRENT CATALOG LISTINGS INCLUDE

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RICHARDS STAPES MASTOID DRILL SET-13-0520 OR 13-0525 (RE-
DESIGNED) CONSISTING OF HAND PIECE, FOOTSWITCH, SETERILIZING
CASE, BURR SET, AND POWER LINE ADAPTOR.
FOOT SWITCH (REDESIGNED) -23-0108

2. WHILE NO DEATHS HAVE BEEN REPORTED, THE DEFECT REPRESENTS
A PRIORITY SITUATION WHICH IS POTENTIALLY LIFE THREATENING.

3. FOREIGN DISTRIBUTION, AS FOLLOWS:

INSTITUT DE SANTE DE L'UNIVERSITE
ALI ABAD
KABOUL, AFGHANISTAN

CLINICA ROMAGOSA SRL
DEAN FUNES 429
CORDOBA, ARGENTINA

BALLARAT BASE HOSPITAL
BALLARAT 3350
VICTORIA, AUSTRALIA

THE MANNING RIVER DIST. HOSPITAL
P.O. BOX 35
TAREE NSW 2430
AUSTRALIA

VICTORIAN HOSPITALS' ASSOC. INC.
188 BATMAN ST.
WEST MELBOURNE 3003 VICTORIA
AUSTRALIA

RAND MEMORIAL HOSPITAL
P.O. BOX 40
FREEPORT, BAHAMAS

SUPPLIES OFFICE
PRINCESS MARGARET HOSPITAL
MINISTRY OF HEALTH
P.O. BOX N 3729
NASSAU, BAHAMAS
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THE QUEEN ELIZABETH HOSPITAL
MARTINDALES RD.
ST. MICHAEL, BARBADOS

KING EDWARD VII MEMORIAL HOSPITAL
HAMILTON, BERMUDA

CLINICA EDUARDO LANE
RUA EDUARDO LANE 200
CAMPINAS, BRAZIL

FACULDADE DE MEDICINA
DA UNIVERSIDADE FEDERAL
GORANIA GOIAS

BRAZIL

INSTITUTO DE ASISTENCIA MEDICA AD
SERVIDOR PUBLICO DO ESTADO
HOSPITAL DO SERVIDOR PUBLICO DO
ESTADO DE SAO PAULO
RUA PEDRO DE TOLEDO 1800
SAO PAULO, BRAZIL

FUNDACAO HOSP. DO DISTRITO FEDERAL
ED PIONEIRAS SOCIAIS 2 ANDAR
BRASILIA DF, BRAZIL

SUPPLY SERVICES
GORGAS HOSPITAL
BOX O
BALBOA HEIGHTS, CANAL ZONE

CENTRAL DE ABASTECIMIENTO DEL
SERVICIO NACIONAL DE SALUD
SANTIAGO, CHILE

CAJA DE LOS SERGUROS SOCIALS
DE ANTIOQUIA
MEDELLIN, COLOMBIA

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HOSPITAL UNIVERSITARIO SAN
VICENTE DE PAUL
MEDELLIN, COLUMBIA

JUNTA DE PROTECCION SOCIAL
DE SAN JOSE
APARTADO 1979
SAN JOSE, COSTA RICA

DEPARTAMENTO MEDICO SEGURD SOCIAL
FLORES 732
ATTN: SERVICIO DE OTOGIA
QUITO, ECUADOR

CENTRO DE EMERGENCIAS
2 DIAG 250 COL LA ESPERANZA
SAN SALVADOR, EL SALVADOR

MEDICA GMBH
BEETHOVENSTR
6602 BUDWEILER, GERMANY

SEVENTH-DAY ADVENTIST CLINIC
P.O. BOX 7226
TAMUNING GUAM 96911

HOSPITAL NACIONAL
JOSE FELIPE FLORES
TOTONICAPAN TOTONICAPAN
GUATEMALA

HOSPITAL ROOSEVELT
GUATEMALA, GUATEMALA

HOSPITAL SAN JUAN DE DIOS
10A CALLE Y 1 AVENIDA
GUATEMALA CIUDAD, GUATEMALA

HOSPITAL HERRERA LLERANDI
6A AVENIDA 8-71 ZONA 10
GUATEMALA - CIUDAD
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DAVIS MEMORIAL HOSPITAL
BOX 596
GEORGETOWN, GUYANA

INNKAUPSTOFNUN RIKISINS
P.O. BOX 1441
REYKJAVIK
ICELAND

SENIOR MEDICAL SUPERINTENDENT
CENTRAL RAILWAY HOSPITAL
BYCULLA BOMBAY 27, INDIA

ARMY HEALTH DEPT.
THE PURCHASING BOARD
AZIA KHAN
TEHRAN, IRAN

PAHLAVI UNIVERSITY
NEMAZEE HOSPITAL
ZAND AVENUE
SHERAZ, IRAN

IRAN RED LION AND SUN SOCIETY
THE CHILDREN'S HOSP. MED. CTR
62 BAYT STREET EISENHOWER AVENUE
TEHRAN, IRAN

DOWNPATRICK HOSP, MANAGEMENT COMM.
DOWNSHIRE HOSPITAL
DOWNPATRICK, IRELAND

SHAARE ZEDEK HOSPITAL
161 JAFFA ST. P.O. BOX 293
JERUSALEM, ISRAEL

TRADIS CO. LTD.
P.O. B - 4239
TEL AVIV, ISRAEL

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TEL AVIV UNIVERSITY
RAMAT AVIV TEL AVIV
ISRAEL

KUPAT HOLIM HEALTH SERVICES
SUPPLY DEPT.
146 DETAH TIGVA ROAD
TEL AVIV, ISRAEL

FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS
VIA DELLE TERME DI CARACALLA
00100
ROME, ITALY

UNIVERSITY HOSPITAL OF THE W.I.
MONA ST. ANDREWS
JAMAICA, WEST INDIES

GHQ JORDANIAN ARMED FORCES
DIRECTORATE ROYAL MED. SERVICES
AMMAN, JORDAN

PROCUREMENT OFFICER
TRUST TERRITORY OF THE PACIFIC IS.
THE PACIFIC ISLANDS
SAIPAN MARIANA ISLANDS 96950

HOSPITAL JOSE A. MUGUERZA SA
AVENIDA FIDALGO NO. 2525 PTD
APARTADO 334
MONTERREY NUEVO LEON
MEXICO

HOSPITAL GENERAL DEL ESTADO
PALACIO DE GOBIERNO

HERMISILLO SONARA
MEXICO

HOSP. SAN JOSE DE MONTERREY SA
AVE. INDEPENDENCIA PTE NO. 3000
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MONTERREY NL MEXICO

ST. ELISABETH HOSPITAL
BREEDESTRAAT 193 O
WILLEMSTAD CURACAS
NETHERLANDS, ANTILLES

JUNTA LOCAL DE ASISTENCIA SOCIAL
HOSPITAL GENERAL DE MANAGUA
MANAGUA, NICARAGUA

HOSPITAL SANTO TOMAS
APARTADO 957 ZONA 1
PANAMA REP DE PANAMA
ATENCION: SRA FLORA DE ORTEGA
JEFE DE CONTABILIDAD

HYOS DE DOMINGO QUERALTO
FUENCARRAL 39 APARTADO 915
MADRID 4, SPAIN

INSTALCIONES CLIICAS
BRAVO MURILLO 79
MADRID 3, SPAIN

SABBATSBERG HOSPITAL
S-11382
STOCKHOLM, SWEDEN

BANGKOK SANITARIUM AND HOSPITAL
430 PITSANULOKE RD.
BANGKOK, THAILAND

EGE UNIVERSITESI TIP FAKULTESI
DEKANLIGI BORNOVA
IZMIR, TURKEY

HACETTEPE UNIVERSITY
PROCUREMENT OFFICE
ANKARA, TURKEY

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MOUNT ALVERNIA HOSPITAL
GUILFORD
SURREY, ENGLAND

ST. GEORGE'S HOSPITAL
CENTRAL SUPPLIES DEPARTMENT
BLACKSHAW RD.
LONDON S W 17, ENGLAND

ROYAL SURREY COUNTY HOSPITAL
FARNHAM RD.
GUILFORD
SURREY, ENGLAND

WESTMINSTER HOSPITAL
THE TREASURER
DEAN RYLE ST. HORSEFERRY RD.
LONDON SWIP 2AP, ENGLAND

ROYAL NATIONAL THROAT NOSE AND EAR HOSP.
THE TREASURER
GARY'S INN RD.
LONDON WCIX 8DA, ENGLAND

ROYAL INFIRMARY
BLACKBURN
LANCS BBE 3LR ENGLAND

MEDWAY AND GRAVESEND HOSPITAL
MANAGEMENT COMMITTEE
CHATHAM
KENT, ENGLAND

NORTH RIDING INFIRMARY
ENT THEATRE
MIDDLESBROUGH
TEESSIDE, ENGLAND

SOUTHAMPTON GENERAL HOSPITAL
STORES DEPT.
COXFORD RD.
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SOUTHAMPTON HANTS, ENGLAND

UNITED OXFORD HOSPITALS

THE STEWARD'S DEPT.
CHURCHILL HOSPITAL
HEADINGTON
OXFORD, ENGLAND

SOUTHMEAD GENERAL HOSPITAL
WESTBURG ON TRYM
BRISTOL, SOMERSET
ENGLAND

THE UNIVERSITY OF LEEDS
RHEUMATISM RESEARCH UNIT
SCHOOL OF MEDICINE
44 CLARENDON RD.
LEEDS LS 29 PJ ENGLAND

VICTORIA CENTRAL HOSPITAL
THEATRE
WALLASEY
CHESHIRE, ENGLAND

DUDLEY ROAD HOSPITAL
THE TREASURER
BIRMINGHAM B18 7QH
ENGLAND

CLATTERBRIDGE HOSPITAL
THE TREASURE
BEBINTON
WIRRLD
CHESHIRE, ENGLAND

EXETER AND MID DEVON HMC
THE TREASURER
45 ST. DAVID'S HILL
EXETER EX 4 4 DN
ENGLAND

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MAIDSTONE AND DISTRICT
HOSPITAL MANAGEMENT COMMITTEE
THE TREASURER
103 TONBRIDGE ROAD
MAIDSTONE, KENT, ENGLAND

HOSPITAL CENTERA DE BARQUISIMETO
C/O SERVICIO DE TRAUMATOLOGIA
BARQUISIMETO, VENEZUELA

INSTITUTO DE OLORRINOLARINGOLOGIA
AV CAJAL NO 48
SAN BERNANDINO
CARACAS, VENEZUELA

4. POSTS ARE REQUESTED TO DETERMINE WHETHER CONSIGNEES HAVE
BEEN INFORMED OF RECALL, DETAILS THEREOF, AND THE CORRECTIVE
MEASURE TO BE TAKEN. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL FACILITIES
Control Number: n/a
Copy: SINGLE
Draft Date: 24 JUN 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE135043
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740167-0846
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19740619/aaaaapss.tel
Line Count: 501
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 10
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: elyme
Review Comment: n/a
Review Content Flags:
Review Date: 29 AUG 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <29 AUG 2002 by PhilliR0>; APPROVED <14 JAN 2003 by elyme>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF MEDICAL DEVICE
TAGS: OGEN, ETRD, TBIO, XX
To: KABUL MULTIPLE
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005